TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
CU000002		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CU2005/000002	18.03.2005	18.03.2004

International Patent Classification (IPC) or national classification and IPC

A61K39/04, A61K39/02

Applicant

INSTITUTO FINLAY – CENTRO DE INVESTIGACIÓN PRODUCCIÓN DE VACUNAS Y SUEROS

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of _____ sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____ , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/ES Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 6–12

because:

☒ the said international application, or the said claims Nos. 6–12 relate to the following subject matter which does not require an international preliminary examination (*specify*):

The present Authority considers that the subject matter of claims 6 to 12 is covered by the provisions of PCT Rule 67.1(iv) relating to methods for the treatment of the human or animal body by surgery or therapy. For this reason, no opinion will be given with regard to the novelty, inventive step and industrial applicability of the subject matter of these claims (PCT Article 34(4)(a)(i)).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
☐ has not been furnished
☐ does not comply with the standard

the computer readable form
☐ has not been furnished
☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-5	YES
	Claims		NO
Inventive step (IS)	Claims	1-5	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-5	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Documents taken into consideration:

D1: EP 0 962 532 A 08.12.1999

D2: TREMBLAY D. et al., "High-level heterologous expression and secretion in Streptomyces lividans of two major antigenic proteins from Mycobacterium tuberculosis". January 2002. Canadian Journal of Microbiology, vol. 48(1) pages 43-48. (01.01.2002)

D3: KIESER T. et al., "Cloning and expression of Mycobacterium bovis BCG DNA in Streptomyces lividans". October 1986. Journal of Bacteriology. Vol. 168(1), pages 72-80 (01.10.1996)

The subject matter of the invention relates to the use of one or more wild, mutant or recombinant strains of *Streptomyces* as the active principle in tuberculosis vaccines, which strains optionally express *M. tuberculosis* antigens.

Document D1 describes a host cell, optionally from genus *Streptomyces*, transformed with a recombinant vector corresponding to an antigenic polypeptide of *M. tuberculosis*.

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Furthermore, document D2 explains how two *Mycobacterium tuberculosis* antigens are introduced into a *Streptomyces* strain. This document indicates the use of *Streptomyces* as a host for the production of recombinant *M. tuberculosis* antigens. However, it does not mention the possible use of *Streptomyces* as a vaccine.

Document D3 describes the similarity between the genes, expression signals and promoters of *Streptomyces lividans* and *Mycobacterium leprae* and *tuberculosis*.

The cited documents do not contain suggestions that might lead a person skilled in the art to the use of *Streptomyces* as a vaccine.

Consequently, the subject matter of said claims is considered to be novel and inventive (PCT Article 33(2) and (3)).

Finally, claims 1 to 5 are considered to comply with the requirement of industrial applicability as defined in PCT Article 33(4).

There are no uniform criteria in the PCT Contracting States for determining whether claims 6 to 12 are industrially applicable. Patentability may also be dependent on the way in which the claims are worded.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The expression "of vaccinal interest" (Spanish text: "de interés vacunal") used in claim 4 is vague and ambiguous and leaves the reader in doubt as to the meaning of the technical features to which it refers. As a result, the definition of the subject matter of said claim is unclear (PCT Article 6).